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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/722,142

11/24/2003

Dan T. Simionescu

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EXAMINER

KUMAR, PREETI

ART UNIT

PAPER NUMBER

1751

MAIL DATE

DELIVERY MODE

05/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/722,142

Applicant(s)

SIMIONESCU ET AL.

Examiner

Preeti Kumar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,21,23,24,28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-21, 23-24, 28-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Non-Final Rejection

1. Claims 20-21, 23-24, 28-29 are pending. Claim 20 is independent.
2. Claims 1-19, 22, 25-27 and 41-46 are cancelled. Claims 30-40 are withdrawn from consideration as being drawn to a non-elected invention.

Response to Amendment

3. The rejection of claims 22, 25-27 under 35 U.S.C. 112, second paragraph, is withdrawn in light of Applicant's cancellation of the claims.
4. The rejection of claims 20-21, 23-24, and 28 under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Adkisson (US 6,645,764) is withdrawn.
5. The rejection of claims 22, 25-27 under 35 U.S.C. 103(a) as being unpatentable over Adkisson (US 6,645,764) is withdrawn.
6. The rejection of claims 20-24 and 28-29 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nimmi et al. (US 5,374,539) is withdrawn.
7. The rejection of claims 25-27 under 35 U.S.C. 103(a) as being unpatentable over Nimmi et al. (US 5,374,539) is withdrawn.

Response to Arguments

8. Applicant's arguments filed in the pre-appeal request have been fully considered. Applicant's arguments with respect to claims 20-29 have been considered but are moot in view of the new ground(s) of rejection.

New Grounds of Rejection

Claim Objection

9. Claim 24 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Tannic acid and tannin are synonyms of one another and accordingly claim 24 does not further limit claim 20.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 20-21, 23-24, 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nimni et al. (US 4,378,224) in view of Nimni et al. (US 5,374,539).

Nimni et al. '224 teach that implant tissues rich in collagen and elastin (see col.4,ln.54-55) selected from the group consisting of tendons, heart valves, pericardium, ligaments, skin, blood vessels, fascia, cartilage and intestine (see col. 2.ln.46-49) are

exemplary starting material for prosthetic devices and teach a method that provides for increase stability for allograft or heterograft implantations.

Nimni et al. '224 teach that to improve the longevity of transplanted devices, they propose, a common stabilization technique involving treatment with tanning agents, such as formaldehyde in the processing of natural tissues. Although heart valves treated with glutaraldehyde can remain functional in situ for many years. However, recent research porcine heart valves indicates that glutaraldehyde preserved implantations can still elicit significant host reactions, including calcification, fibrin deposition and an anaphylactic response. See col.1,ln.15-27.

Nimni et al. '224 do not teach crosslinking with the claimed phenolic tannin and recites tanning agents in general.

Nimni et al. '539 teaches animal tissue selected from tendons, heart valves, pericardium ligaments, skin, blood vessels, fascia, cartilage, and intestine can be crosslinked using standard bifunctional crosslinking reagents, such as natural tannins and glutaraldehyde. See col.5,ln.40-45 and claims 9-11. Nimni et al. '539 provides motivation to one of ordinary skill in the art to crosslink the fibrillar network with tanning reagents to preserve their structure, and decrease the ionic strength thus allowing the molecules to disperse into a suspensions of monomeric or polymeric collagen. It has been noted that such treated tissues become lighter in color and more pliable, an effect that is particularly evident after such matrices are crosslinked with bifunctional reagents such as glutaraldehyde (0.2% solution). See col.4,ln.20-30. This teaching of pliability property achieved with the tannin illustrates the presence of elastin within the tissue and

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encompasses the material limitation to the claimed implantable fixed tissue exhibiting at least 60% less calcification over being fixed with glutaraldehyde.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to arrive at an implantable fixed tissue including a residue of phenolic tannin crosslinking agent because Nimni et al. '224 in combination with Nimni et al. '539 teach pericardial tissue crosslinked with natural tannin to produce a pliable, implantable bioprosthesis. One of ordinary skill in the art would have been motivated to combine the teachings of Nimni et al. '224 with that of Nimni et al. '539 because both references teach the analogous art of stabilizing heart valve implant tissue with tanning agents for improved transplantations.

13. Claims 20-21, 23-24, and 28 are rejected under 35 U.S.C. 103(a) as obvious over Adkisson (US 6,645,764) in view of Asculai et al. (US 6,444,222).

Adkisson clearly indicated that the neocartilage compositions are useful as implants and as replacement tissue for damaged or defective cartilage. See Abstract, third paragraph, first sentence. Adkisson teaches neocartilage matrix of skeletal muscle and other connective tissue is fixed with glutaraldehyde and tannic acid. See col.6,ln.1-10 and col.14,ln.11-12. Adkisson teaches that the neocartilage may be mammalian neocartilage, including human and porcine, or avian neocartilage. See col.10,ln.42-50.

Adkisson teaches neocartilage matrix of skeletal muscle and other connective tissue fixed with glutaraldehyde and tannic acid. See col.6,ln.2-3.

In example 4, Adkisson teaches fixing neocartilage with tannic acid and subsequent sterilization following addition of tissue transglutaminase. The animals within

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example 4 showed excellent tolerance of the surgical implants and good adherence of grafts to surrounding tissue. Since, the prior art teaches fixing with tannic acid and surgical implants within the same example, the language of "sterile neocartilage" does not exclude the neocartilage fixed with tannic acid in the same example one paragraph above. Adkisson teaches that the neocartilage does not require the inclusion of three-dimensional scaffolds, However, such scaffolds can also be used, if desired but either way the cartilage is strong yet malleable. See col.9,ln.50-55.

Adkisson is silent to the claimed fixed tissue comprising crosslinked elastin. Specifically, in table III, Adkisson describes that the neocartilage implants were found to contain type II, type IX and type XI collagen (see col.9,ln.63) but the reference is silent on the neocartilage tissue containing elastin.

Asculai et al. teach collagen type II is reinforced with elastin protein scaffolds in the analogous art of providing mechanical stability that is essential in tissue implantations. See col.3,ln.30-37.

It would have been obvious, to one of ordinary skill in the art, at the time the invention was made, to arrive at the claimed implantable fixed tissue comprising phenolic tannin crosslinked elastin, with a reasonable expectation of success, since the teachings of Adkisson suggest neocartilage comprising type II collagen fixed with tannic acid and Asculai et al. teach the beneficial utility of reinforcing type II collage with elastin protein scaffolds in the analogous art of making an implant.

One of ordinary skill in the art would have been motivated to combine the teachings of Adkisson with that of Asculai et al. since the primary reference suggest the

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inclusion of protein scaffolds in general and the secondary reference teaches the beneficial utility of elastin protein scaffolds in cartilage comprising type II collagen.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Preeti Kumar whose telephone number is 571-272-1320. The examiner can normally be reached on M-F 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Douglas Mc Ginty can be reached on 571-272-1029. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Preeti Kumar *PK*
Examiner
Art Unit 1751

PK

Douglas M Ginty
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